Testimony of

R.H. Barry Sample, Ph.D.
Director of Science and Technology
Employer Solutions
Quest Diagnostics Incorporated
before the
Oversight and Investigations Subcommittee of the
Committee on Energy and Commerce
U.S. House of Representatives
on
Products that Claim to Prevent Detection of Certain Substances by Drug Testing Programs

May 17, 2005

Executive Summary

Quest Diagnostics' Employer Solutions division performs more than 8 million drug tests annually in its network of six SAMHSA-certified labs. Trends in workplace testing are reported semi-annually in the Quest Diagnostics Drug Testing Index (DTI). The written report that follows examines the trends as reported in the DTI and describes in more detail the impact and costs of products designed to defeat the accuracy of urine drugs tests. Key findings and observations include:

- We have observed a gradual decline followed by a leveling off in the positivity rate of workplace drug tests – from a high of 13.6%, in 1988, to 4.5%, today
- Our data suggests that simply having a comprehensive drug testing program has a deterrent effect on drug use and the more frequently an individual is eligible for a drug test, the lower the positivity rate.
- Based on our data and data from the National Survey of Drug Use and Health, suggests that the prevalence of drug use in the past month among the employed U.S. population is approximately 50% greater when there is no employer sponsored drug testing program.
- In 2004, approximately 52% of the workplace drug tests performed by Quest Diagnostics included optional comprehensive specimen validity testing. The remaining 48% of the tests are at risk because the employers did not request comprehensive specimen validity testing that including oxidizing adulterants.
- Drug positive specimens are more than two (2) times more likely to have a low creatinine (potentially indicative of a *dilute* specimen).
- In a recent study, we found that approximately an equal number of specimens that contained marijuana or cocaine metabolites (regardless of the cutoff) had low creatinine values. This means that some of those above the cutoff were unsuccessful attempts at dilution and some of those below the cutoff are suggestive of successful attempts at dilution.
- The additional direct cost our laboratories incur to perform additional analysis based on specimen validity test results indicating potential adulteration or dilution is estimated to exceed $500,000 annually.
- The additional direct cost to employers for collection and other non-laboratory components of a second specimen due to "invalid" specimens is estimated to be over $1,000,000 annually!
- Just by providing an invalid specimen, the donor will be buying enough time to clear the drugs from his or her system and thus naturally produce a negative drug test on the second collection.

Options to combat "anti-drug testing" products include:

- Legislation to prevent the distribution and use of these products and devices
- Performing specimen validity tests at the collection site

- Performing additional analysis in the laboratory, without regard to administrative cutoffs, if a "suspicious" specimen is detected.
- Requiring a recollection for all dilute as well as invalid specimens.

Background

Quest Diagnostics is the leading provider of diagnostic testing, information and services that patients and doctors need to make better healthcare decisions. The company offers the broadest access to diagnostic testing services through its national network of laboratories and patient service centers, and provides interpretive consultation through its extensive medical and scientific staff. Quest Diagnostics is a pioneer in developing innovative new diagnostic tests and advanced information technology solutions that help improve patient care.

The Quest Diagnostics Employer Solutions division is dedicated to providing innovative solutions to meet a company's employee screening needs. As the leading provider of drug testing services in the nation, our unparalleled experience can help reduce a company's exposure to risk with the following comprehensive screening services and employee health management solutions.

Laboratory-based Drug Testing Options
Specimens are tested at one of our six national Substance and Mental Health Services Administration (SAMHSA)-certified laboratories. In addition, each laboratory maintains the licenses or certifications to meet applicable Federal, State, and local laws and regulations.

Alternative Specimen Testing
In addition to urine testing, we offer hair and oral-fluid tests for drugs of abuse at two of our laboratories

Adulterant Testing
With the recent development of specimen adulteration products, specimen adulteration threatens even the most stringent drug testing programs. Specimen donors may either ingest these foreign substances, sometimes promoted as cleansing agents, or they may add them to urine specimens with the goal of preventing drug use detection. With our TestSure™ adulterant testing process, we are able to detect a wide variety adulterants that may be added to a urine specimen in an attempt to beat the drug test.

Healthcare Professional Panels
Addressing potential drug abuse by healthcare professionals, we offer a healthcare professional panel to detect a wide variety of narcotics and sedatives that might be abused by professionals or other workers in the healthcare industry.

Steroid and Athletic Drug Testing
We perform steroid and athletic drug testing specifically designed to detect performance-enhancing agents including anabolic steroids. We also provided the anti-doping analyses for the Centennial Olympic Games held in Atlanta in 1996.

On-site Drug Testing Options
We offer the option of on-site specimen collection and testing, and a portfolio Quest Diagnostics branded point of collection test devices, to deliver immediate results in support of time-critical decision-making efforts.

Collection Services
We have a national network of more than 1000 Quest Diagnostics-owned Patient Service Centers that can perform collections for the detection of the drugs of abuse complemented by an additional network of more than 600 third-party collections sites.

Employee Wellness Programs
We also offer Employee Wellness Programs designed to lower healthcare costs through health risk assessments and clinical testing.

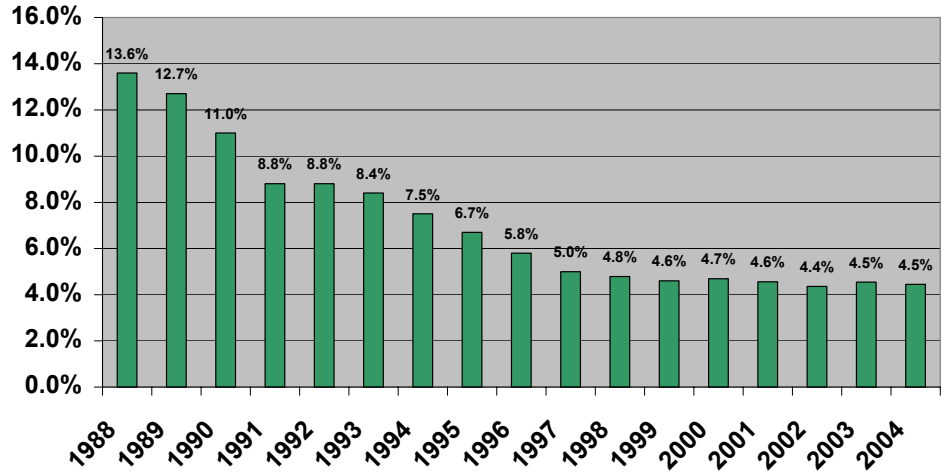
OSHA
We offer testing for employee exposure to potentially hazardous substances in the workplace.

Overall Drug Testing Trends

Each year, Quest Diagnostics Employer Solutions Division performs over 8 million drug tests. The Drug Testing Index (DTI), which we publish semi-annually as a public service to government and industry, summarizes the results of workplace drug tests performed by Quest Diagnostics. We have published the DTI since 1988. The DTI examines positivity rates among three major testing populations: Federally-mandated safety-sensitive workers (FMSS); the general workforce (GW); and the combined U.S. workforce. Workers in the FMSS category include airplane pilots, bus and truck drivers, railroad workers, and workers in nuclear power plants, for whom routine drug testing is mandated by the U.S. Department of Transportation (DOT) and the Nuclear Regulatory Commission (NRC). Since the DTI focuses on prevalence rates in *workplace* drug testing, it excludes tests performed for medical reasons, including rehabilitation and monitoring programs; criminal justice settings; and tests submitted for confirmation of drug tests conducted at the point of collection. The most recent release of the DTI includes and summarizes the results of over 7.2 million workplace drug tests performed in 2004.

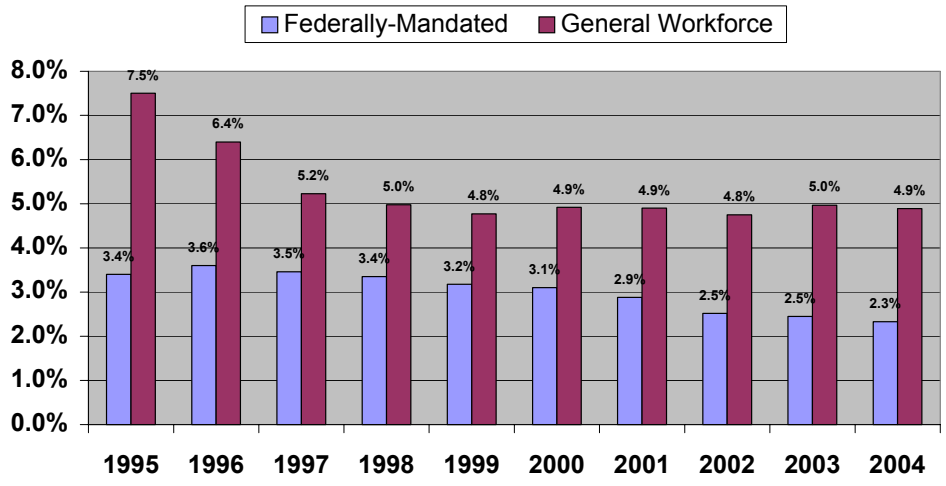
Since the inception of the DTI in 1988, we have observed a gradual decline followed by a leveling off in the positivity rate in these workplace drug tests – from a high of 13.6%, in 1988, to 4.5%, today (See **Figure 1**)

Figure 1: Annual Positivity Rates for Combined U.S. Workforce



There has been little change in the overall positivity over the last 5-6 years. However, we do observe differences in the positivity rates between the General Workforce (GW) and the Federally-mandated Safety Sensitive (FMSS) testing (See **Figure 2**)

Figure 2: Annual Positivity Rates by Testing Category



This difference in positivity rates between the two groups may be due to the greater testing rates in the FMSS group. The two major types of testing reasons – pre-employment and random – between 2001 and 2004 are summarized in the **Table 1**, below.

Table 1: Percent of Specimens Tested by Testing Reason, 2001-2004

	Federally-Mandated Safety Sensitive (N=4.7 million)	General Workforce (N=23 million)
Pre-Employment	45%	79%
Random	43%	9%
Other	12%	12%

This data, in combination with the positivity rates, suggests that simply having a comprehensive drug testing program has a deterrent effect on drug use and the more frequently an individual is eligible for a drug test, the lower the positivity rate. This hypothesis is also supported by data from the annual National Survey on Drug Use and Health (NSDUH) conducted by the department of Health and Human Services. The table below compares positivity rates from the DTI and population estimates of reported drug use in the previous month from the NSDUH in 2002 and 2003.

Table 2: Comparison of Positivity Rates and Reported Drug Use Between the Quest Diagnostics Drug Testing Index and the National Survey on Drug Use and Health, 2002-2003

Data Set	Group[3]	Any Illict[4]		Marijuana	
		2002	2003	2002	2003
NSDUH[1]	Any Program	7.4%	7.0%	5.3%	5.3%
NSDUH	No Program	10.3%	10.4%	8.3%	8.5%
DTI[2]	FMSS	2.5%	2.5%	1.4%	1.3%
DTI	GW	4.8%	5.0%	2.9%	3.0%

[1] U.S. Dept. of Health and Human Services, Substance Abuse and Mental Health Services Administration, Office of Applied Studies. NATIONAL SURVEY ON DRUG USE AND HEALTH, 2002-2003 [Computer file]. ICPSR version. Research Triangle Park, NC: Research Triangle Institute [producer]. Ann Arbor, MI: Inter-university Consortium for Political and Social Research [distributor].

[2] Quest Diagnostics Drug Testing Index

[3] For the NSDUH, "Any Program" is defined as a "Yes" answer to the question: "Does your workplace ever test its employees for drug use"

[4] For the NSDUH, "Any Illicit" drug use is defined as use of marijuana, hallucinogens, heroin, cocaine, inhalants or psychotherapeutics in the past month.
For the DTI, in the Federally-mandated safety sensitive (FMSS) group, the rate shown is full-year overall positivity for amphetamines, cocaine metabolite, marijuana

metabolite, opiates, or phencyclidine, adulterants, or substitution. In the general workforce (GW) group, it is full-year overall positivity for barbiturates, benzodiazepines, methadone, methaqualone, propoxyphene, or the analytes included in the FMSS group

On the basis of the NSDUH data, the prevalence of drug use in the past month among employed respondents appears to be approximately 50% greater when there is no employer sponsored drug testing program. Comparing the DTI (General Workforce) and NSDUH prevalence rates, one might conclude that the DTI underestimates drug use among employed workers by 50% or more. Part of this difference in "positivity" rates may be explained by timing differences – most drugs measured by the DTI are cleared by the body, depending on usage patterns, in a matter of days and thus a urine sample would not be positive; whereas, the NSDUH asks about drug use in the previous 30 days. Another factor that might explain the difference in positivity rates is the requirement for administrative cutoffs in workplace drug testing – most drug testing programs are designed to ***deter*** drug use rather than ***detect*** all possible drug users. Thus, the presence of a drug metabolite in the urine below a cut-off value is not reported as a positive drug test. Finally, another factor to consider are donors that attempt to "beat the drug test" by using a variety of products designed to subvert the testing process.

Specimen Validity Testing and Adulteration

Products designed to assist donors in beating a drug test can be broken down into three broad categories – ***"cleansing" agents***, ***adulterants*** added to a specimen, and ***devices***. The "cleansing" agents include "teas", "detoxifiers", "shampoos", and "mouthwashes", in addition to water. Shampoos and mouthwashes are designed specifically to try to subvert hair and oral-fluid testing, respectively. The teas and detoxifiers were developed originally for urine drug tests and many are now marketed for all types of drug tests. While the product themselves are not likely to actually "clean" or "wash away toxins", the user is usually instructed to consume anywhere from 32 to 64 oz of fluid as a part of the "cleansing" process. Since workplace drug tests usually have administrative cutoffs,or limits below which a drug test is considered negative, this ***"internal dilution"*** may lower the concentration of drug or metabolite in the urine below the reporting threshold. Occasionally, donors may also attempt either ***"external dilution"*** or *substitution* of the urine with water or other liquids, in the privacy of the restroom.

Adulteration of urine specimens has been attempted by donors, probably as long as there have been urine drug tests. In the early days of drug testing, this would typically involve the use of household products easily available to a specimen donor, e.g., bleach, vinegar, drain cleaner, lye, soap, etc. One of the first "commercial" products for adulteration of a urine specimen was Urinaid (glutaraldehyde). When laboratories first began performing basic tests of specimen validity, we saw limited evidence of adulteration. By the late 1990's, there was an explosion of these products along with constant evolution (Urine Luck, Whizzies, Instant Clean ADD-IT-ive). Most of these products are in a group known as ***"oxidizing adulterants"***. These oxidizing compounds can interfere with the detection and/or confirmation of marijuana metabolite in a

urine specimen. Since marijuana has consistently represented 50-60% of all positives reported in the DTI, oxidizing adulterants can be a serious issue.

In addition to the "cleansing agents" that are consumed by a donor and adulterants that are added to a urine specimen, there now are devices sold that enable a donor to provide a totally clean, negative urine – that is not their own – in the privacy of the bathroom or other private collection area. Currently, the verification of specimen validity at collection sites relies on inhibiting access to water, soap, or other products that might be used to adulterate a specimen; asking the donor to display the contents of their pockets; prohibiting the taking of purses, briefcases or similar personal items into the bathroom; and the measurement of specimen temperature. By using devices which may be concealed under the donor's clothing, the donor is able to provide a "certified negative", "clean" urine that will pass the temperature check. Many of these devices are sold with "heat activators" or "thermocouples" to either maintain the temperature or heat the sample to the desired range of 90°-100°F. Other devices, such as the "Zip N Flip" detoxifying bag, require the donor to urinate into a bag, mix the urine to remove the "toxins" and then pour the urine into the collection container. The best mechanism for thwarting these devices is a directly observed collection – but, for many reasons, this is not a practical or attractive solution.

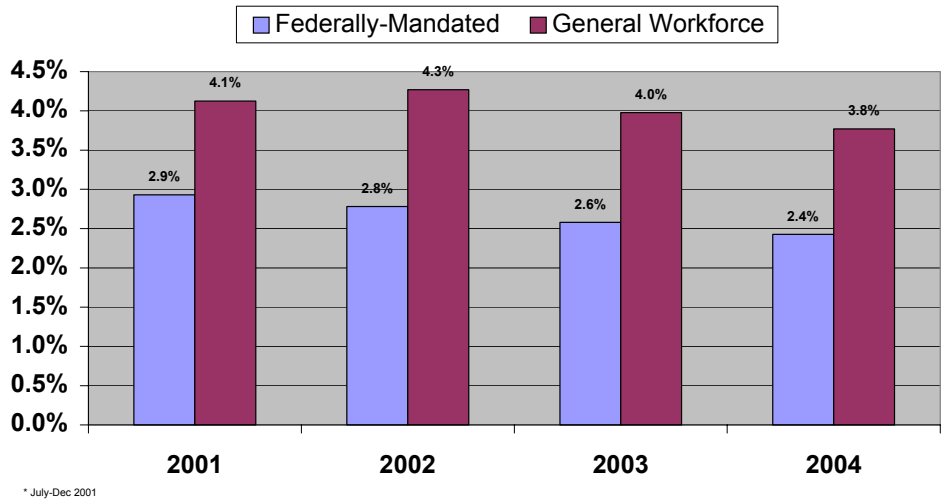
After the specimen arrives at the laboratory for testing, laboratories assess *"specimen validity"* by performing a group of tests known collectively as specimen validity tests (SVT). The Department of Health and Human Services, in the Mandatory Guidelines for Federal Workplace Drug Testing Programs (69 FR 19644), has recently modified the requirements for SVT to now require tests for creatinine and specific gravity, when indicated (as indicators of dilution and substitution); for pH (an indicator of acidity/alkalinity); and for oxidizing adulterants. The new rules also modified certain of the cutoffs and testing methodology requirements for SVT. Quest Diagnostics has routinely tested for creatinine, specific gravity, when indicated, and pH on all specimens for many years. In addition, since 1998 with our TestSure™ process, we have offered specimen validity tests including testing for oxidizing adulterants and alternative screening technology, when indicated. Unfortunately, other than the recent change in standards for testing Federal employees, comprehensive SVT is not required even for the Federally-mandated testing performed either under DOT rules (49 CFR Part 40) or NRC rules. Some of the reluctance to require SVT on the part of both these Federal agencies and the private-sector is the added cost of performing specimen validity tests. On average, these tests cost employers $1.00-$2.00 more than a drug screen with only basic SVT. ***In 2004, approximately 52% of both the private-sector and Federally-mandated workplace drug tests performed by Quest Diagnostics included comprehensive SVT testing.***

Dilution & Substitution

The parameters measured to determine if a specimen is ***dilute*** or ***substituted*** are creatinine and specific gravity. Creatinine is a normal metabolic product of muscle metabolism, is normally present in everyone's urine, and has long been used clinically as an indicator of urinary dilution. Specific gravity is a measure of dissolved particles in urine and is also an indicator of urinary

dilution. A dilute specimen is one that has a creatinine less than 20 mg/dL and a specific gravity less than 1.003 ***and*** does ***not*** fulfill the criteria for a substituted specimen. Quest Diagnostics has been specifically tracking the incidence of all dilute specimens since July 2001 and the trends are shown in the **Figure 3** below:

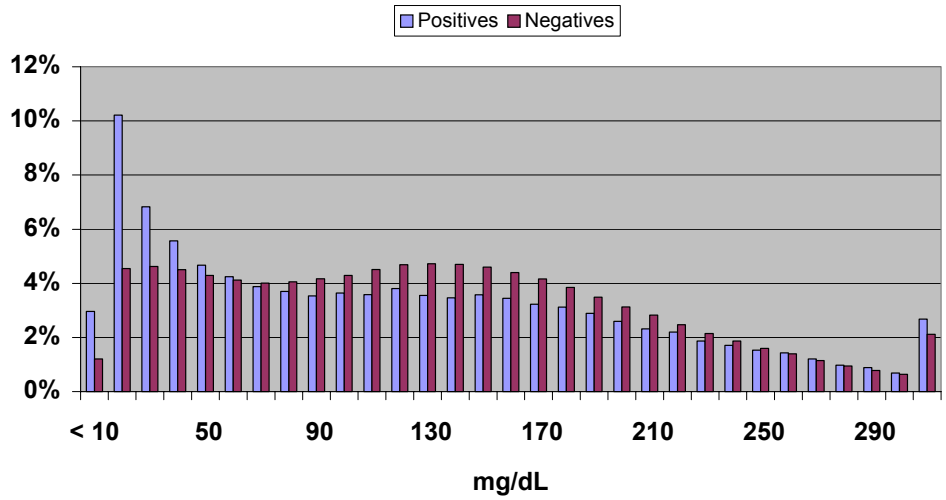
Figure 3: Annual Dilute Rates by Testing Category, 7/2001-2004



Deleted: <sp>

Of note, however, is the potential impact of dilution and fluid intake on drug test results. Between 1999 and 2001, we performed three separate data collections where the distribution of creatinine concentrations in positive and negative specimens was determined. Shown below (**Figure 4**) is a chart comparing the distribution of creatinine concentrations in nearly 2,000,0000 negative specimens and 80,000 urine specimens from general workforce employees and applicants:

Figure 4: Distribution of Creatinine Concentrations in Negative and Positive Specimens



There appear to be two different distributions of creatinine values – one for positives and one for negatives – with positive specimens being skewed towards lower creatinine concentrations. In fact, based on this data, it would appear that a drug positive specimen is more than two (2) times more likely to have a creatinine <20 mg/dL (one of the two factors in the definition of a *dilute* specimen) and there is a significant difference in the proportion of positive specimens with a creatinine <20 mg/dL. **These individuals may be viewed as those that tried to dilute, but failed.**

In another smaller study (N~500,000) conducted in 1998, we examined those specimens that exhibited a response, both above and below cutoff, on the initial (screening) test for either cocaine metabolite or marijuana metabolite. These two analytes were selected since they both have very high (>97%) confirmation rates and those specimens not confirming almost always contain drug at a concentration less than the confirmation cutoff. A comparison of the detection rates and incidence of a creatinine less than 20 mg/dL is shown in the **Table 3** below:

Table 3: Detection Rates on the Initial Test for Marijuana and Cocaine Metabolites and Incidence of Low Creatinine Values in Each Group

		Drug Detection Rate	Creatinine <20 mg/dL
Overall			6.0%
Marijuana Metabolite	Below Cutoff	2.6%	14.7%
	Above Cutoff	3.5%	11.7%
Cocaine Metabolite	Below Cutoff	1.0%	8.1%
	Above Cutoff	0.9%	10.2%

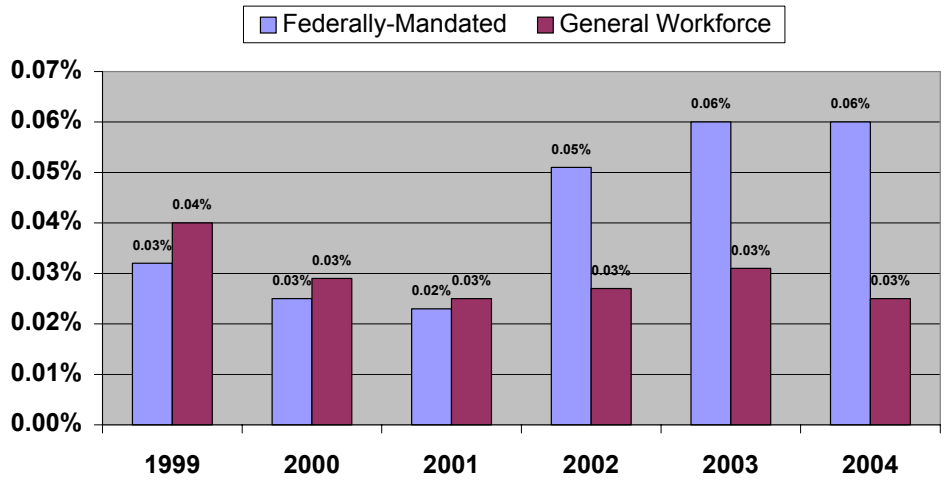
The data for the above cutoff specimens is consistent with that presented above and with the general workforce DTI results. However, the notable point is that in specimens suspected of containing marijuana or cocaine metabolites, ***there were approximately an equal number of specimens that contain drug at a concentration less than the cutoff*** as there were above the cutoff. In the case of marijuana metabolite, there is an even higher incidence of low creatinine specimens among those below the cutoff. Thus, some percentage of specimens containing marijuana metabolites below the cutoff and with a low creatinine may be viewed as having been ***successfully diluted.***

A Substituted specimen is defined (69 FR 19644) as: "A urine specimen with creatinine and specific gravity values that are so diminished or so divergent that they are not consistent with normal human urine." The criteria used by laboratories for reporting a substituted specimen are:

Creatinine < 2 mg/dL & SG <1.0010 *or*
Creatinine < 2 mg/dL & SG $\geq$1.0200

Prior to the effective date of the revised HHS rules and publication of the laboratory guidance documents in November 2004, the creatinine cutoff for a substituted specimen was 5 mg/dL as specified in HHS Program Document #35 (9/28/1998). The trends in substituted specimens are shown in the chart (**Figure 4**) below:

Figure 4: Annual Substituted Rates by Testing Category, 1999-2004



Dilute and substituted specimens also have an impact on laboratory costs, MRO costs and employer costs. Every specimen with a low creatinine (<20 mg/dL) requires a reflexive specific gravity with an estimated annual Quest Diagnostics laboratory cost of over $400,000. In addition, the recent regulatory changes (11/2004) now require the use of a 4-place refractometer to measure specific gravity on all specimens with a specific gravity <1.0020 or are determined to have been substituted. This regulatory change requires ***all*** federally certified drug testing laboratories to purchase new instrumentation for these specimen validity analyses. For the network of Quest Diagnostics laboratories, this represented a capital expenditure of approximately ***$100,000***.

A negative-dilute specimen may require additional review and in some private-sector employer programs, a negative-dilute result is not considered a valid result, which could require an additional drug screen with the incumbent collection and laboratory costs. Furthermore, for DOT-mandated testing, a specimen that is "ultra-" or "hyper-" dilute (i.e. with a creatinine between 2 and 5 mg/dL and specific gravity of > 1.0010 and <1.0030), triggers an immediate observed collection. The average cost for an observed collection is $100-$150 not including the additional cost for laboratory analysis or MRO review of the additional specimen.

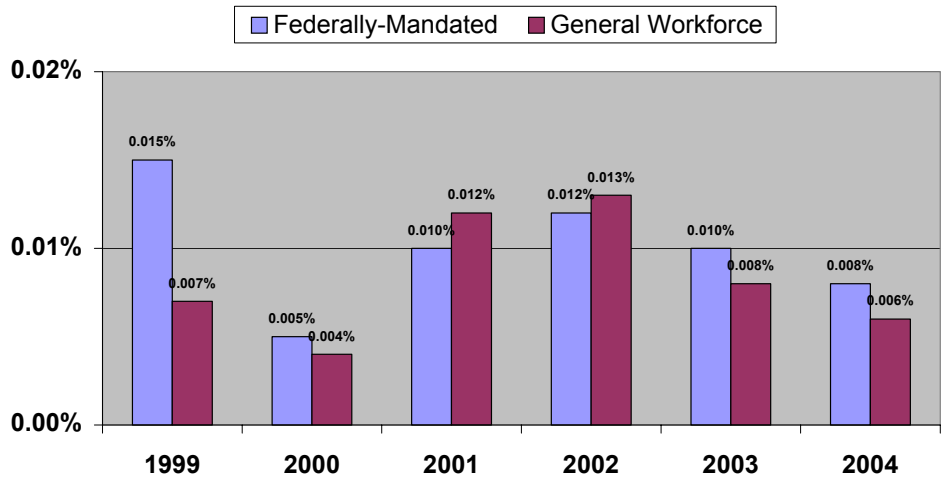
Some specimens may also be reported as ***Invalid*** based on the creatinine and specific gravity results. These specimens have abnormally low creatinine or specific gravity values and do not meet the criteria for a substituted specimen. All of these invalid specimens, as well as the substituted specimens, require additional (confirmatory) analysis on a second portion of the original urine specimen. This confirmatory testing is projected to cost approximately ***$100,000***, in 2005 – reflecting a nearly ***three (3) fold increase*** in the number of specimens requiring

additional specimen validity analyses since the new HHS criteria were implemented in November 2004.

Adulterated and Invalid

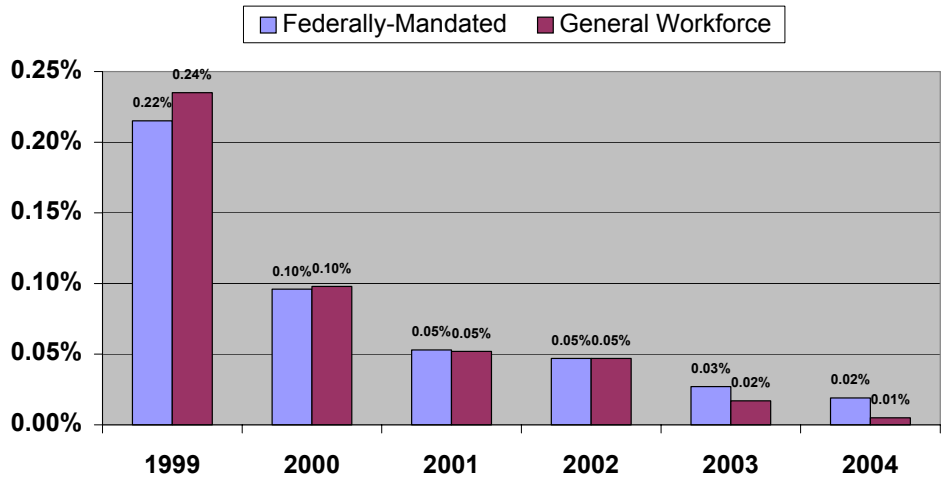
The two most commonly detected types of adulteration detected by Quest Diagnostics are caused by altered specimen pH (acidity) or oxidizing adulterants. While pH adulteration has occurred for many years, its prevalence rate has remained low and relatively constant (see **Figure 5** below).

Figure 5: Annual Acid/Base (pH) Adulteration Rates by Testing Category, 1999-2004



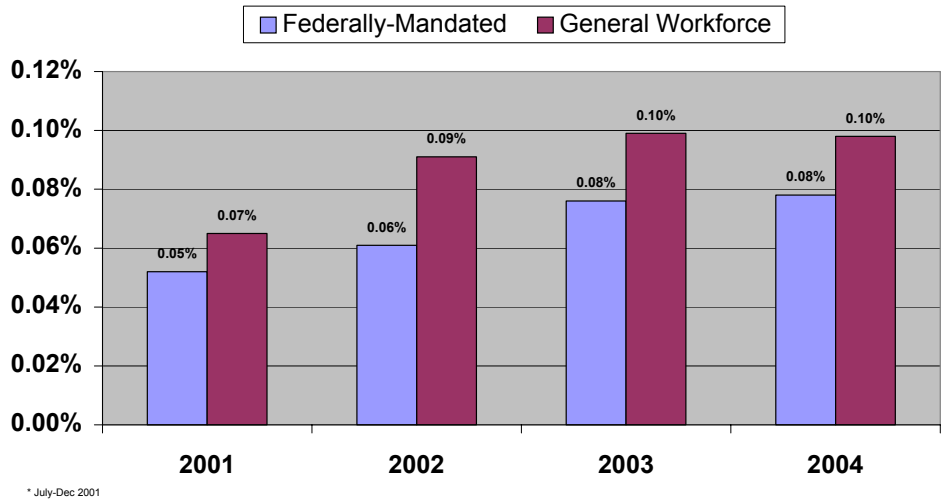
In contrast, the rate of occurrence of oxidizing adulterants has shown marked change over time as the adulterant industry and donor awareness of laboratory testing capabilities have evolved. In 1998, the use of nitrites, Urine-Luck™, and other products exploded in the marketplace, and the "positivity" rate for these adulterants was very high (>0.5%). However, as testing for oxidizing adulterants evolved in response to the evolution of the adulterant industry, the "positivity" rate for adulteration declined as shown in the chart(**Figure 6**) below:

Figure 6: Annual Oxidizing Adulterant Rates by Testing Category, 1999-2004



This chart does not tell the whole story behind this decline. While some of the decline is due to laboratories' ability to detect adulterants, some of the decline is also due to the changing nature of the adulterant products. In addition to changing the type of oxidizing adulterant in an attempt to evade laboratories' efforts at identification, some providers of these products developed "cocktail" products. This approach combines several different adulterants, none of which would exceed the laboratory reporting threshold, resulting in, at worst, an invalid result. Overall, if one looks at the incidence of all invalid specimens – to include an invalid result due to abnormal oxidant activity (where the adulterant is not identified or is below the reporting threshold), abnormal pH, abnormal creatinine or specific gravity, abnormal odor, etc., – the incidence of invalid specimens has been increasing over time (see **Figure 7** below):

Figure 7: Annual Invalid Rates by Testing Category, 7/2001-2004

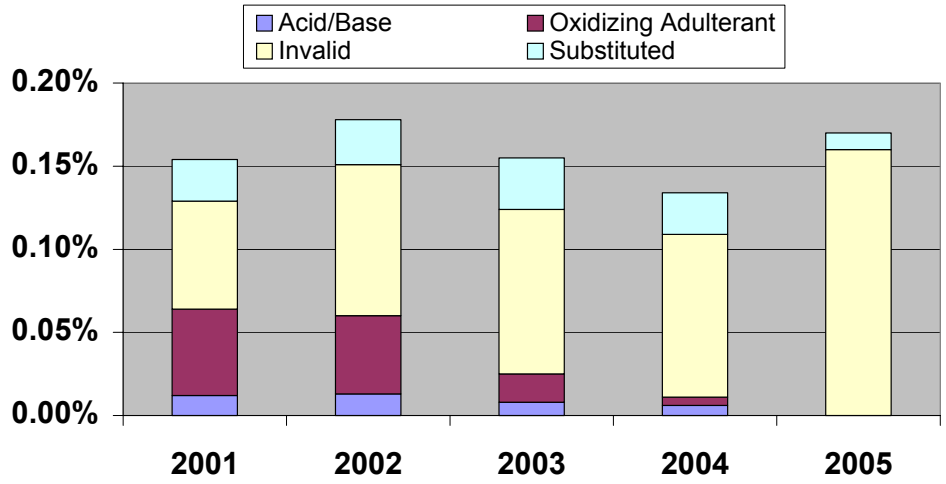


Like dilute and substituted specimens, adulterated specimens also have an impact on laboratory, MRO and employer costs. Every specimen with an abnormal pH on the initial test requires that the laboratory perform a reflex test on that aliquot of urine using different technology with a greater dynamic range. In addition, specimens shown to have an abnormal pH and/or abnormal oxidant activity on the initial test require that the laboratory perform a confirmation test on a separate aliquot of urine. All of this additional testing costs our laboratories approximately $50,000, annually. Every specimen reported as either adulterated or invalid incurs additional costs for MRO services; and, in the case of an invalid specimen, usually requires an additional observed specimen collection and laboratory analysis and MRO review.

Overall Trends in Specimen Validity Testing

The chart below show the combined incidence of general workforce specimens that were reported as adulterated, substituted or invalid between mid-2001 (when we started uniformly tracking all of these parameters in conjunction with the laboratory statistical reporting requirements of 49 CFR Part 40) and April 2005:

Figure 8: Annual Adulterated/Substituted/Invalid Rates in the General Workforce, 7/2001-4/2005



We believe that one of the reasons for the recent large increase in incidence of invalid specimens is the recent regulatory change in the criteria and required technology for reporting substituted, invalid, and adulterated results (especially due to the presence of oxidizing adulterants). The other reason is the increasing sophistication of "anti-drug testing" products that make it more difficult for the laboratory to identify a specific adulterant. If one assumes that only 50% of the invalid specimens reported by our laboratories do not have an "alternative medical explanation" and require a second collection under observed conditions, ***the additional direct cost to employers for collection, testing, and review of a second specimen would be over $1,000,000 annually!*** Furthermore, just by providing an invalid specimen, the ***donor will be buying enough time*** to clear the drugs from his or her system and thus naturally produce a negative drug test on the second collection. Moreover, since the majority of private-sector testing programs do not include random testing, these individuals will be able to resume their drug-using habits after the test, putting themselves and their co-workers at risk